Bringing it all together

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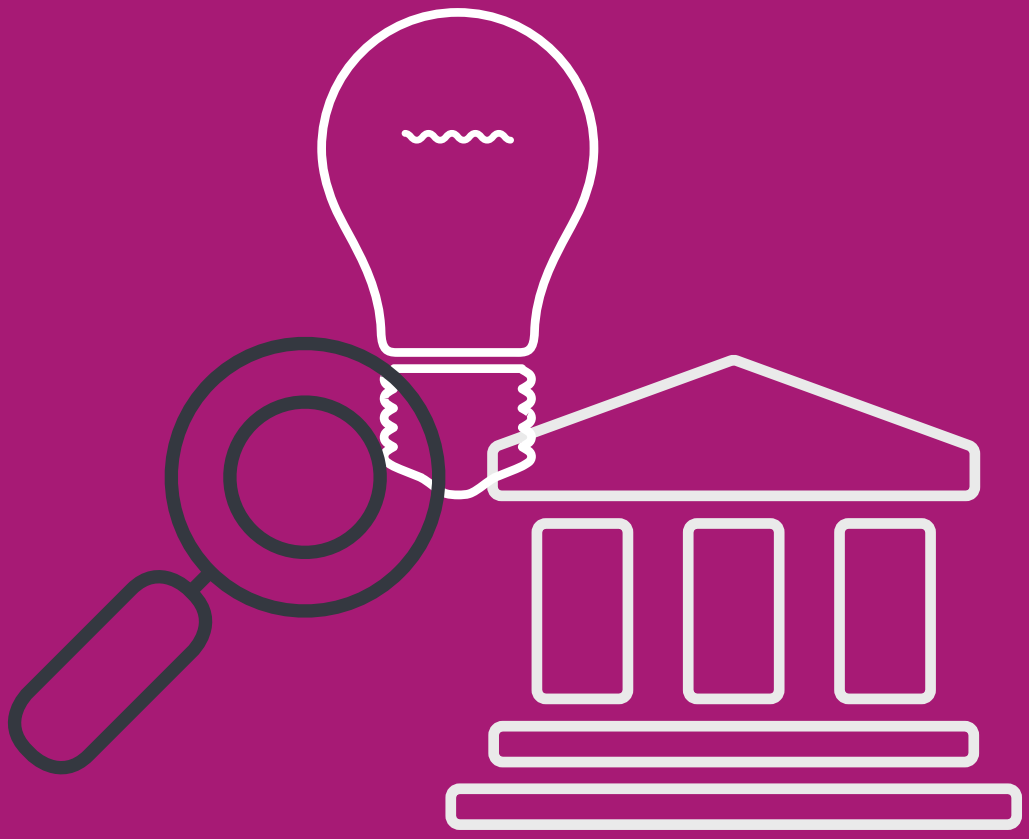

CHAPTER 11: BRINGING IT ALL TOGETHER

The complexity of innovation governance systems — from the focus on risk-related policies and public engagement, to the rigidity of product regulatory frameworks — helps us to avoid potentially hazardous developments, but it also stifles potentially useful innovation.

Risk and innovation are contested topics in most fields of human endeavour. As the preceding chapters have shown, wherever one looks there is great variation, between and within nations and societies, in the ways we perceive the risks and benefits from innovations and in the ways we govern them. However, the prevailing expectation in most societies is that there will be a continuing trend in the development of innovations that will improve our lives through economic, health-related or environmental benefits[1]. And the risk governance processes we choose to put in place for innovative technologies will determine not just which products and processes are developed, but also what scale of company can participate in their development and ultimately the competitive advantage of nations and regions[2].

Given the importance of innovation to us all, we need a good understanding of how public and stakeholder pressures interact with risk regulatory systems and of how both stakeholders and regulators then guide innovation, encouraging some developments and closing off others. Specialist expertise is required in a range of contexts: to provide the evidence needed to make competent decisions on risk regulation, to conduct fair and equitable stakeholder engagement, or to develop an innovative product or process. But there is also an important requirement for a balanced generalist overview to understand how these specialisms and influences interact with one another in ways that can either be detrimental to, or support, particular innovations. In making decisions on risk regulation for advanced innovative technologies, regulators have often ignored the impacts of their decisions on innovative capacity and have, until very recently, given little consideration to how 'smarter' regulatory approaches could deliver safety and efficacy more cheaply and rapidly than current regimes. This is particularly the case for companies developing chemicals, pharmaceuticals, health care products based on regenerative medicine, pesticides, genetically modified (GM) crops and products based on nanotechnology and synthetic biology.

This chapter considers how issues of risk, trust, politics, benefits, engagement and regulation have combined to create the environment in which today's innovators must operate. The two decades spanning the transition from the twentieth to the twenty-first centuries saw the emergence and implementation of a new governance agenda that has had very considerable political influence. It has radically altered the innovation environment, particularly in areas of technology development that are likely to be publicly contested, with mixed outcomes and in many cases suboptimal delivery of public benefits from new scientific discoveries[3].

Regulation and the new governance agenda

Towards the end of the twentieth century, building on research in the social sciences, the concept of governance (the process of governing) began to shift in response to pressures from: the emergence of unexpected problems with technologies previously considered safe; a decline in public trust of government bodies and industry; the rapid pace of scientific development and technological change; the difficulties policymakers had in keeping up with this pace of change; and commercial pressures arising from globalization[4]. Two distinct academic disciplinary perspectives contributed to the development of this new governance agenda with little overlap among academic participants or literature cited, but with a common focus on the development of more participative, democratic decision making processes.

The first, led by academic policy researchers, envisaged a change in the role of the state from top-down regulation to a new governance style based on greater participation by non-governmental actors. The state changed from being the main implementer and controller of policy outcomes to facilitating and coordinating interaction between the various interests involved[5], giving rise to metaphors such as the 'hollowing out of the state'[6] or 'steering not rowing'[7]. The presumption was that government, having set the parameters in terms of the policy goals, then delegated to others how those goals were to be achieved. These ideas were developed in a general policy context and the literature makes little reference to risk and innovation, but they were influential across all policy areas and created a receptive policy space for the ideas emerging from the second academic perspective.

The second strand of academic thinking that contributed to the new governance agenda arose in science and technology studies (STS) and focused very strongly on issues of risk and innovation. It challenged the authority of science, particularly its presumed impartiality and its role as provider of public benefits. This strand of STS thinking was concerned about the undemocratic nature of this dominance of science on government decision making and sought to change the political landscape, again towards greater public participation in regulatory decision making[8]. Two related factors in STS thinking were particularly important in delivering the political influence they sought: (i) questioning the authority of scientific expertise and the validity of scientific

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evidence used to support policy and regulatory decisions by government[9]; and (ii) focusing much of their discourse on uncertainty and risk with the precautionary principle (or approach) being seen as the policy answer to this challenge.

Alongside this new bottom-up governance agenda, in technology-related areas there is still a need for regulation based on top-down command and control, backed up by sanctions and penalties to regulate the safety to human health and the environment of innovative products and of the processes used to develop them. As the governance agenda was bringing in a softer, more participative approach, existing regulatory regimes were changing in the opposite direction. Each time a new form of risk has been found in a class of products, a new layer or branch has been added to the regulatory system to ensure that future products will be safe from that type of defect. For example, following the discovery of birth defects caused by thalidomide, all new drugs were required to be tested for teratogenicity. In pesticide development, the damage to wildlife caused by organochlorine insecticides led to the rejection from development pipelines of any new pesticide that was likely to be persistent in the environment. As a result, the products in use today have never been safer. However, the regulatory systems themselves have become more complex, more time consuming and considerably more costly for the companies that need to work with them (it now takes approximately 10 years, and up to £300 million, to cover the regulatory requirements for a new GM crop variety and up to £1 billion for a new drug).

The shift to a new governance approach towards the end of the twentieth century can thus be seen as the addition of a new form of oversight for industry sectors that were already bearing a heavy and increasing regulatory burden. Indeed, there has been an increase in the complexity of the

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operating environment for innovators to accommodate the new focus on engagement and dialogue and to come to terms with the difficulties regulators have experienced in operationalizing the precautionary principle[10]. These issues are part of the background to the case study on GM crops in this chapter, and would be relevant to the alternative risk management strategy that it outlines. A possible example of such an approach, bringing together evidence-based regulation along with a continuing emphasis on openness and engagement, is given in the case study in Chapter 6 on changes to pig inspection.

Participatory processes

Emerging from the new perspectives on risk governance and the emphasis on participative democracy, stakeholder engagement has become an essential requirement for

TABLE 1

The implications and outcomes related to engagement on the basis of interests and ideology (minds and hearts)[15].

Interest-based engagement (minds)	Uncommitted members of the public	Ideology-based engagement (hearts)
Restricted to specific developments		Spreads across related and sometimes unrelated developments
Location specific, locally organized		Organized nationally or internationally
Conflict can usually be resolved by: • providing information • giving compensation • negotiation		Conflict is very difficult to resolve: • information is treated as propaganda • compensation is seen as bribery • negotiation is seen as betrayal
Giving concessions leads to mutual accommodation		Giving concessions leads to escalation of demands
Negative events lead to adjustments in products and processes		Responses to negative events are disproportionate

scientists undertaking innovation-related research and for companies developing the resulting products and processes. The emphasis on uncertainty and precaution among STS academics led, in the first decade of this century, to the promotion of 'upstream engagement' as a key component of the new governance agenda. The think-tank Demos, in a policy publication advocating upstream engagement[11], made clear its political ambitions: "the task is to make visible the invisible, to expose to public scrutiny the assumptions, values and visions that drive science", and "… reshape … the very foundations on which the scientific enterprise rests".

Psychologists tell us that where issues are remote from society (as in upstream engagement or the development of truly novel technologies), citizens are more likely to engage with an issue on the basis of values or ideology rather than local personal interest[12]. In such cases, conflict and polarization of views are more likely to arise and resolution of any conflict will be more difficult to achieve[13] (see Table

CASE STUDY

A CASE HISTORY ON GM CROPS

David Baulcombe (University of Cambridge)

The first generation of genetically modified (GM) crops has delivered diverse and well-documented benefits. They have helped to stabilize soil and increase the efficiency of water use. They have also reduced pesticide toxicity for farmworkers and beneficial insects, and increased the profitability of agriculture in regions as diverse as India (GM cotton) and Hawaii (GM papaya).

The potential for benefit from GM is further enhanced by research in universities, institutes and companies, which have produced an extensive range of additional GM traits. These traits could improve the sustainability of crop production, or they could improve the quality of the crop products for nutrition or industry. In the near future there are exciting new genome editing methodologies that will further reinforce the transformative potential of GM in global agriculture. The detailed description of these potential benefits is described in a report produced for the UK government's Council for Science and Technology[1].

A European logjam on GM

However, the full benefits of these GM traits are yet to be realized, especially in European Union, because complicated regulatory and approval processes have deterred commercial interest and excluded non-commercial applications. Only three GM crops have been approved for commercial cultivation in Europe since 1990 (ref. 2). An application for a GM maize (Dupont Pioneer's TC1507) was made in 2000, but is still in limbo even though the line is very similar to a previously-approved variety. In the United States, there have been 96 commercial GM approvals since 1990 and a healthy stream of applications to the regulatory process. Australia has approved 12 GM crops since 2002 (ref. 1).

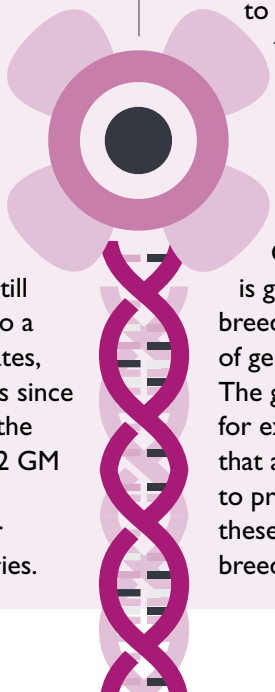
Europe has a global leadership role and our logjam suppresses innovation in other countries. These countries may model their GM approval process on that of Europe, or they may prohibit GM crops because they are concerned that their cultivation would restrict their opportunity to export non-GM crops to Europe[3].

Risk and hazard in the European Union's regulatory process

The current EU regulation of GM crops has two stages. First the European Food Safety Authority (EFSA) assesses an application and expresses an opinion based on scientific evidence on whether a crop under evaluation is safe. If EFSA delivers a favourable safety opinion, the European Commission will then prepare a draft decision to authorise commercial cultivation, which is considered and voted on by an official EU committee of representatives from the Member States.

This process is expensive and time consuming, however, because it is based on the presumption of hazard. The process also has to be implemented in full for each application, irrespective of whether the GM trait is associated with any risk. The United States has a more streamlined regulatory process for the commercial release of a GM crop, but even there it can cost US$7 million to US$14 million (in 2007 prices)[4] — an amount that is prohibitive for small- and medium-sized enterprises. In Europe the costs could be greater, and innovation is correspondingly less likely.

The inappropriateness of the current EU approval process is illustrated by comparing GM with conventional plant breeding. There is great uncertainty associated with conventional breeding, because there is an unanticipated degree of genetic variation between closely related plants. The genomes of maize plants in a breeders cross, for example, may each have several hundred genes that are absent from the other parent[5]. It is difficult to predict the consequence of interactions between these genes in the hybrids produced by a conventional breeding programme. Further complications arise in



1). In essence, the more developed a particular application towards its end purpose, the more deliberative and meaningful the conversation is likely to be. When citizens are unfamiliar with the issues at stake, engagement processes — whether upstream or downstream — can thus become a process of framing these unfamiliar developments, either favourably or unfavourably, in the public mind, potentially giving considerable power to those who conduct the engagement[14].

conventional breeding because there may be epigenetic effects on gene expression in a hybrid plant that persist for many generations[6] after the initial hybridization event.

GM may also involve similar genetic and epigenetic uncertainties, but to a much more limited extent because there will normally be only one or a few transgenes in each line. One response to this comparison would be to introduce additional regulation for conventionally bred crops. However, the past experience of thousands of years of breeding — including modern breeding for the past hundred years — illustrates the absurdity of that conclusion. A more rational response would be to use conventional breeding as a benchmark: additional assessment would be appropriate if there is plausible additional risk associated with the GM trait relative to a conventionally bred variety.

The inappropriate differentiation of GM and conventional crops is illustrated by several recent examples in which the crop carries a transgene that could have been transferred by conventional breeding[7], albeit through a process that would take longer than with GM. The GM crops with the new gene would be subject to the EFSA/EU approval process, whereas the conventionally bred variety with the same gene would not, although the risks to health or the environment would be similar with both types of plant.

An alternative risk management strategy in crop improvement

A revised strategy for innovation in EU crops would have a more risk- rather than hazard-based structure than the current process. It would take into account the evidence that there is no inherent environmental or nutritional hazard in the process of genetic modification, and it would also consider the risks associated with the failure to innovate. It is unlikely that small revisions to the current process are likely to achieve an outcome that promotes innovation towards a sustainable agriculture of crops — instead, a new process should be derived based on the principles of risk assessment as applied in other industries. Where risks are difficult to quantify, it would be appropriate to implement GM-specific procedures only if the risk is assessed as being greater than with an equivalent variety produced by conventional breeding.

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These points are raised in the Annual Report of the Government Chief Scientific Adviser 2014. Innovation: Managing Risk, Not Avoiding It under the heading 'Anticipating the Challenges', where it is noted that the categories of innovation likely to lead to the most heated discussion are (i) where the wider benefits of an innovation are accepted but where highly local costs and impacts are imposed, and (ii) where the debate is largely about values. Table 1 illustrates some of the characteristics of dialogue under these contrasting circumstances, demonstrating why value- or ideology-based conflicts are most difficult of all to resolve (as continues to be the case for GM and related technologies).

Despite such problems, the initial assumption of scientists and science funders was that upstream engagement would, if managed properly, improve public acceptance of new technologies and would not bring an end to any area of research[16]. However, as noted above, Demos[17] expected upstream engagement to have profound implications for the future of science and to reshape the way that science relates to public decision making. Although upstream engagement has been widely undertaken, for example by UK research councils[18, 19], Demos' ambitions have not yet been achieved. Also, there is not yet any evidence that better public acceptance of new innovative technologies will result from such engagement and in practice there have been reductions in funding for some areas of science and innovation, particularly in nanotechnology[20] and plant biotechnology, arising from political influences and policy makers' concerns about negative public opinion rather than evidence of potential or actual harm. As noted in case study on GM crops, such considerations have also influenced the extent to which GM crops are being cultivated in Europe[21].

Another presumption has been that, through the new governance approach, policy-makers would simultaneously engage with a wider range of stakeholders and also base their decisions on better quality evidence. A common tactic among the diverse groups and networks of stakeholders

CASE STUDY

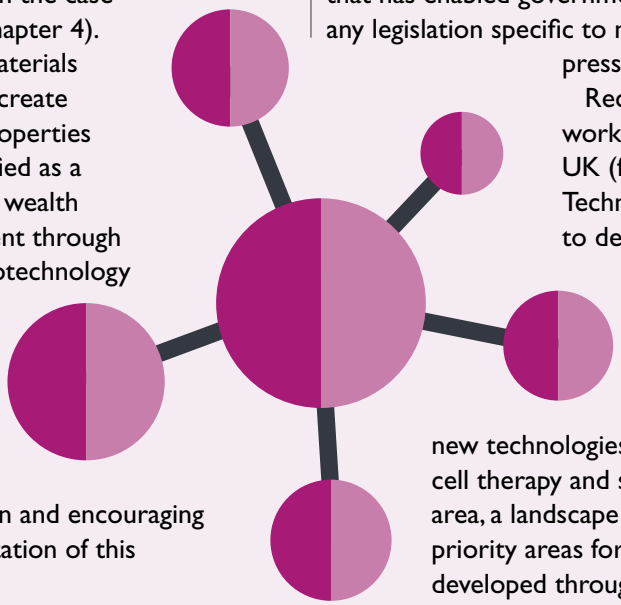
STANDARDS: SUPPORTING EMERGING TECHNOLOGIES AS AN ACCELERATOR OF INNOVATION

Scott Steedman (Director of Standards, British Standards Institution)

Positioned alongside regulation, voluntary consensus standards that have been developed with full stakeholder engagement and open public consultation can provide an invaluable tool to share information and to build trust in new and emerging technologies. Although the use of standards as an accelerator of innovation is well understood in other major economies (notably in Germany, where standards play a strong part in the activities of the Fraunhofer institutes), in the United Kingdom there is a poor understanding of the potential for standards to act as alternatives to regulation. This important tool is therefore frequently ignored in UK innovation strategy and planning.

Standards provide a powerful alternative to regulation in many areas, but can be particularly effective in supporting new and emerging technologies where public trust needs to be maintained. One particular case study, which shows the effectiveness of standards building up over time, is the emergence of nanotechnology (as outlined in the case study by Kamal Hossain in Chapter 4).

The ability to manipulate materials at very small length scales to create products with higher-value properties and functions was first identified as a potential source of significant wealth creation by the UK government through its creation of the LINK Nanotechnology Programme in the 1980s. This was followed by the Taylor Report on nanotechnology[1] in 2002, which recommended that the government should invest in stimulating innovation and encouraging successful commercial exploitation of this technology.



At the same time, public concern was growing over the potentially unknown and unquantified risks associated with nanomaterials, particularly in relation to the possible hazards they posed to humans and the environment. Environmental pressure groups demanded that the technology should be subject to stronger regulation.

In 2004 the British Standards Institution (BSI)[2], in its role as the UK National Standards Body, pioneered the development of the first international standards committee on nanotechnologies, as well as a UK standards committee to mirror this work. These bodies developed strategic plans that highlighted the three main priorities for standards development:

- Terminology and Nomenclature
- Measurement and Characterization
- Health, Safety, and Environment

Since then the expert committees have developed a number of standards, including vocabularies, occupational health and safety guides, toxicity testing standards, and characterization test methods. Laboratories testing against these standards can be accredited by the United Kingdom Accreditation Service (UKAS) to provide further confidence in the emerging technology. The development of these standards of best practice is one important factor that has enabled governments to avoid introducing any legislation specific to nanotechnologies, despite pressure to regulate the industry.

Recently, BSI has been working closely with Innovate UK (formerly the government's Technology Strategy Board) to demonstrate the value that timely standardization can bring to priority areas such as offshore renewable energy, assisted living (such as new technologies to support the elderly), cell therapy and synthetic biology. In each area, a landscape and roadmap that identifies priority areas for new standards was developed through a process of stakeholder engagement in a similar way to that used for nanomaterials ten years ago.

The success of this approach is increasingly widely recognized. Investment is now needed to extend the concept so that standards advice becomes permanently embedded within the Catapult technology and innovation centres, as well as research communities across the United Kingdom.

that engage with policy decisions on risk and innovation is to promote exclusively the evidence that supports their objectives or even to manufacture such evidence[22]. This is an inevitable part of political processes but, as noted above, upstream engagement tends to push dialogue towards issues of value and ideology and in such cases there is much less willingness on the part of protagonists to reconsider evidence on the basis of its scientific merit[23] (Table 1). Such challenges downgrade the value of research findings as evidence to support decision making and policymakers are finding that science and technology in some areas are becoming less governable as the evidence base for decisions is challenged and eroded.

Impact on innovation

Technology foresight has contributed to government support for the development of innovative technologies for over 30 years, but human capabilities in this area are notoriously flawed. Now, based on the new governance agenda we have included risk foresight (through the precautionary principle) and foresighting public needs and desires (through upstream engagement). In the case of advanced innovative technologies with product lead times considerably longer than five years, the uncertainty inherent in foresight becomes multiplied several-fold. The governance-based approach, promoted in a spirit of optimism as a means to achieve more democratic and more robust political processes and decisions, has distributed power more equitably across societal groups — but this has, in many cases, resulted merely in greater complexity and confusion, and longer delays in decision making.

There were sound reasons behind the changes in policy decision making outlined above. However, evidence is now beginning to accumulate that the complexity we have introduced into our governance systems through the upstream focus of risk-related policies and engagement, coupled with the increased complexity and rigidity of product regulatory systems, is stifling potentially useful innovation in addition to the desired impact of avoiding potentially hazardous developments.

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For example, the more complex, lengthy and expensive our governance systems become, the more innovation becomes dominated by large multinational companies[24]. As observed in the GM crops case study, no small company with an innovative idea can hope to reach a market without doing so through a large multinational company, through selling the intellectual property, a straightforward buy-out or some other form of collaboration. Small companies therefore develop their business models with such outcomes in mind, leading to a focus on innovations that are likely to fit with the strategies of the large companies. These companies in turn will be most receptive to incremental innovations that will enable them to improve on their current products or processes by making them more efficient or more sustainable. Path-breaking, disruptive innovations that could potentially contribute to pressing societal needs will either meet with self-censorship by scientists and innovators or will fail to attract funding along their development pathway. The paradox here is that the domination of the agrochemical and pharmaceutical industry sectors by large multinational companies, so strongly criticized by environmental advocacy groups, is a direct result of the kind of regulatory system that they themselves have been instrumental in encouraging.

A comparison between the recent innovation experience of information and communication technologies (ICT), where there have been several waves of disruptive innovation over the past twenty years, and life sciences where innovation has been largely incremental despite enormous public investment in the basic science, illustrates this point. Likewise, failure by large multinational companies to develop products to meet evident human needs (new antibiotics to address the challenge of antibiotic resistance, or GM crops to control pests and diseases in non-commodity crops) relates to the incompatibility of such developments with current industry business models that are a direct result of the regulatory systems that apply in these sectors.

The new governance agenda and upstream engagement are probably here to stay, but we have yet to learn how to

accommodate their combined pressures in a way that will circumvent their potentially corrosive impact on innovative developments that could meet important societal needs.

A more adaptive approach to the governance of risk and innovation

During the twentieth century, the focus of innovation moved from chemistry to information and communication technologies, and the bio-economy is now expected to be the growth engine of the twenty-first century. The innovation trajectories in each of these areas are (or will be) very different, but research on 'what works' in innovative business models, taking account of the complexity in the innovation environment arising from new governance approaches, has been very limited. Likewise, there has been little socio-economic research on the interactions between risk regulatory systems and innovation, as opposed to the very large amount of research on the new governance agenda.

It is becoming increasingly clear that our governance systems for advanced innovative technologies are not always fit for purpose. Product regulatory systems that have built up by a process of slow accretion over a period of years are now so onerous that even multinational companies are finding it difficult to develop new innovative products. The new governance agenda was intended to improve policy and regulatory decisions by making them more democratic. Instead it has led to a less democratic and less evidence-based system, in which risk regulation and restriction of specific areas of scientific and innovative activity are seen by some governments and policy makers, particularly in the European Union, as valid responses to societal pressures or the need for public reassurance, rather than a means of dealing with risks for which there is an evidence base[25].

Until recently, flaws in regulatory systems related to over-regulation of innovative products and processes have not been a matter of great concern for governments, except where there has been public pressure to address such problems, as in the case of the accelerated development of drugs to treat AIDS. This is in contrast to considerable government attention to the need for 'better regulation' in non-risk related areas. In a state of ignorance, or at least insouciance, the assumption has been that this hidden tax on innovation processes can be accommodated by companies while still delivering products at an affordable price. This chapter has focused on the areas where the current risk governance deficits are greatest and where the need for systemic change is most pressing, for example in areas linked to the bio-economy, but these challenges may spread in the near future to other advanced innovative technologies.

Such systemic factors can mitigate against effective decision making in at least two ways: (i) the system can become so amorphous and unstructured that there is no clear basis for decisions and also no clearly identified locus for decision making; or (ii) it can become so complex, rigid and constrained by legal and customary precedent that it is incapable of adapting to new threats or opportunities. The bio-economy is in danger of experiencing the first of these threats in the context of the new governance agenda and the second in the context of conventional risk regulation.

> There has been little socio-economic research on the interactions between risk regulatory systems and innovation.

Therefore recommendations related to the adoption of a precautionary approach (see the 'NGO Perspective' in Section 2's fracking case study) should elicit a broad-based policy response that takes account of the interests and values of protagonists and the costs and benefits of alternative options, as outlined in Chapter 4's neonicotinoid pesticide case study. In a similar vein, the case study on bisphenol A in Chapter 3 points to the need for an increased focus on scientific evidence as a basis for regulatory decision making even, or perhaps particularly, where this is undertaken within the European Union's overall precautionary regulatory system.

Changing the behaviour of innovation or regulatory systems will require finding the right policy levers that will adapt or re-align the relevant system components, and new smarter approaches to regulation and governance are the most likely pressure points to deliver better innovation-related value for money from public investment in basic science.

The two case studies included in this chapter provide very interesting pointers to future directions that could be taken to meet these needs. Standards developed through dialogue between stakeholders and companies, to ensure the quality of products and processes and to govern health, safety and environmental impacts, have a much better record of being adaptive in the face of new technological developments than our current regulatory systems (see nanotechnology case study). This is not to suggest that standards could totally replace these regulatory systems, but much could be learned from the adaptive processes they have used so successfully.

The alternative risk management strategy proposed for novel crops by David Baulcombe (see GM crops case study) could be a starting point for re-thinking the European regulatory system in a way that would be sufficiently radical to enable re-shaping and reinvigorating of innovation for European crop production. Each approach has the potential to complement the other, and together they could enable us to deploy our insights more intelligently than we have done to date.

The above commentary should not be seen to counsel against the elements of the new governance approach or engagement, upstream or downstream. However, we need to learn how to overcome these systemic threats without jeopardizing the safety and effectiveness of the innovative products and processes that we will need to meet future societal challenges.